



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/324,343	06/02/1999	JOHAN H. GEERKE	ALZA-0022 ARC-2865-R3	1409
23377 7590 01/17/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/17/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/324,343	Applicant(s) GEERKE ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 32-33, 35-36, 38 is/are rejected.
- 7) ☒ Claim(s) 34 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 9/1/2006. Claim(s) 1-38 are pending. Claim(s) 1-17, 21-31 have been withdrawn. Claim(s) 18-20, 32-38 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 18-20, 32-33, 35-36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al US Patent 5,248,310 in view of Wong et al US Patent 5,785,994 and Riddle et al US Patent 5,294,770.
2. The instant claims are directed to three-layer tablets comprising a first and second layer that contains a drug and at least one colorant, and a third layer containing a second and different colorant. The dependent claim further adds a coating layer to said tablets and methylphenidate chloride as the active ingredient.
3. Barclay teaches osmotic tablets comprising separate drug polymer and polymer layers wherein each layer is distinguishable from each other by a different color. Barclay specifically teaches the use of colorant to allow appropriate color contrast between

Art Unit: 1617

layers of his formulation (see abstract, col 20, lines 26-60; col 7, lines 59-col 8, line 34). Barclay shows that coloring agents are used in the art for determining the formulation orientation. (see col 17, lines 20-56). At col 17, lines 20-55, Barclay describe an osmotic tablet comprising a white color drug containing layer and a reddish brown hydrophilic polymer layer. Barclay teaches the non-drug polymer layer to contain a reddish-brown color (see col 17, lines 40-44). Barclay describes the use of ferric oxide colorant as the colorant of choice. Barclay then compresses the drug and non-drug layer together and coats the resultant solid osmotic tablet with a translucent coating. (see col 17, lines 39-51).

Barclay coats the tablet with a translucent coating and describes that the drug/beneficial agent layer is detectable through such translucent coating (col 5, lines 42-51). Since color difference is easily detectable by naked eye, Barclay's tablet inherently possesses capability to be detected by a colorant detector. In fact, Barclay detects or observes the white drug-containing layer from the reddish-brown polymer-layer in the tablet. (see col 17, lines 52-54). After detecting which side of the tablet contains the drug layer (in another words, detecting the orientation of the tablet), Barclay chooses to drill a passage whole through the drug-containing layer for delivering the drug from the osmotic tablet. (see cool 17, lines 55-57). Therefore, Barclay teaches the use of colorant for purposes of detecting orientation of a two layered osmotic tablet.

Barclay also teaches suitable size or shape for his tablets to allow comfortable oral delivery. (see col 6, lines 20-24, figures 1-3). Such suitable shapes include

Art Unit: 1617

capsule- shaped tablets as depicted in figure 1-3 of Barclay's Patent. Barclay also teaches the use of methylphenidate hydrochloride as a suitable drug in his formulation. (see col 11, lines 13-15). Barclay does not teach a three layer osmotic tablet.

Barclay only fails to explicitly teach a three-layered tablet and further use a color detector to orient the tablet formulations. However, preparing a two or three layer osmotic tablet and using a color detector to orient a tablet are well within the level of an ordinary skill in the art.

4. Wong and Riddle are respectively used to show the general knowledge in the art to make three layer tablet or use a color detector to orient tablet formulations during their manufacturing process.

5. Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay. Wong teaches a three or more layered tablet that provides a varying pattern of drug release (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation. Wong et al. disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong also describes methylphenidate as a suitable drug in his formulation (col 10, line 21). Wong essentially teaches similar tablets as Barclay.

Wong teaches three-layered osmotic tablets containing a port (see abstract). At least one layer of Wong's tablets contains a dye such as ferric oxide. Wong discloses tablet dosage forms comprising three layers wherein first layer is drug free and is a push layer which contains a colorant such as ferric oxide (see col 17 line 23; col 20,

Art Unit: 1617

lines 20-25) and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). Thus, adding additional drug layers is well within the scope of Wong's teachings.

The tablet of Wong comprises an exit port (see col 17 line 56) meeting the limitation of claims 25, 30 (see col 15 lines 15-18). Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong also describes methylphenidate as a suitable drug in his formulation (col 10, line 21). Wong essentially teaches the same tablets as Barclay. Except that Wong is a three or more layered tablet that provides a varying pattern of drug release. (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

6. Barclay and Wong are within the same field of endeavor and therefore their teachings are combinable. Barclay employs aspirin, steroids, methylphenidate, etc... (see col 11, lines 1-65, examples 1, 3 and 5). Wong also employs the same drugs (see Wong at col 10-col 11, lines 7-8).

Barclay describes hydrophilic polymers and hydrogels as suitable polymeric units (see col 13, lines 23-67). Wong also teaches the same polymeric moieties (see Wong at col 12, lines 44-col 13, line, 65).

Barclay teaches osmagents such as magnesium sulfate etc...(see col 13, lines 4-20). Wong teaches the use of the same osmagents (see col 5, lines 33-50).

Barclay uses the ferric oxide as the colorant in the polymeric layer (see example 2). Wong also uses ferric oxide as a colorant in his polymeric layer (col 17, lines 18-26).

The only difference between Barclay and Wong is that Barclay teaches a two layer osmotic tablet, but Wong teaches a three layer osmotic tablet. Nevertheless, their combined teachings do not explicitly teach the use of a color detector during their manufacturing process.

7. Riddle is used to show that using a color detector is a well recognized practice in the art of orienting tablet formulations during their manufacturing process. (see abstract, fig 1B, col 5). Riddle explicitly states that the orientation of tablets is recognized typically by their color differences on the side of tablets (see col 7, lines 10-60; specifically col 7, line 30-31). Riddle further states that his detector can be used in any tablet treatment process, which can include the step of creating a delivery port (see col 1-2; col 7, line 35-col 8, line 32). Thus using a color detector in the art has been practice at least since 1992.

8. Therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because the ordinary skill in the art would have had a reasonable expectation of success to use different colorants to facilitate ease of detection of each formulation layer and even further employ a color detector such as those described by Riddle to differentiate the orientation of the tablets during their manufacturing process for any suitable step such as creating a delivery port.

Allowable Subject Matter

9. Claims 34, 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant argues that the cited references do not disclose a tablet having a drug/drug/no drug orientation three-layer tablet structure. Specifically, the Barclay patent does not disclose a dual drug orientation. The proposed combination of Wong and Barclay patents would yield a different structure, having a no drug/drug/no drug orientation.

This is not persuasive because Applicants have misinterpreted the references. The combination of the cited references does indeed form a drug/drug/no drug orientation three-layer tablet structure. Barclay clearly discloses a tablet with a drug layer and no drug layer. Barclay only fails to explicitly teach a three-layered tablet. However, preparing a two or three layer osmotic tablet are well within the level of an ordinary skill in the art.

Wong and Riddle are respectively used to show the general knowledge in the art to make three layer tablet or use a color detector to orient tablet formulations during their manufacturing process. Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay. Wong teaches

Art Unit: 1617

a three or more layered tablet that provides a varying pattern of drug release. Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

Therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because the ordinary skill in the art would have had a reasonable expectation of success to use different colorants to facilitate ease of detection of each formulation layer and even further employ a color detector such as those described by Riddle to differentiate the orientation of the tablets during their manufacturing process for any suitable step such as creating a delivery port.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

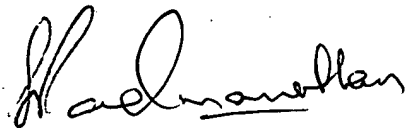
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER